



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857Re: EXCENEL® Sterile Suspension  
Docket No. 96E-0269

NOV 21 1996

#18

Stephen G. Kunin  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
U.S. Patent and Trademark Office  
Box Pat. Ext.  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,902,683 filed by Pharmacia & Upjohn Company under 35 U.S.C. § 156. The animal drug product claimed by the patent is EXCENEL® Sterile Suspension (ceftiofur hydrochloride), New Animal Drug Application (NADA) No. 140-890.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use for food producing animals of this product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F.Supp. 1224 (E.D. Va. 1989), aff'd, 894 F.2d 392 (Fed. Cir. 1990).

The NADA was approved on April 26, 1996, which makes the submission of the patent term extension application on June 24, 1996, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Martha A. Gammil  
Pharmacia & Upjohn  
Intellectual Property Services  
301 Henrietta Street  
Kalamazoo, MI 49001